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Subject: OCSPP News for November 12, 2020

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EPA issues hot-button guidance for risk assessment

E.A. Crunden, E&E News

https://www.eenews.net/greenwire/2020/11/11/stories/1063718255?utm_campaign=edition&utm_medium=email&utm_source=eenews%3Agreenwire

After a yearslong delay, EPA has released a long-delayed draft handbook offering guidance on developing key chemical safety assessments.

The Integrated Risk Information System (IRIS) program yesterday released the handbook, following a delay that has drawn criticism from industry members who say IRIS processes and assessments lack transparency. EPA last delayed the release of the handbook this summer.

IRIS assessments are not regulations, but they can influence EPA decisions as well as private-sector behavior. Toxicity values derived by IRIS assessments are used at every level of government and play a role when considering cleanups at contaminated sites.

In recent years, the IRIS study of formaldehyde, a known carcinogen, prompted concerns that the Trump administration's assessment was compromised due to a political appointee with deep industry ties.

The draft lays out 13 procedures for developing IRIS assessments in a document spanning almost 300 pages, with the intent of establishing consistent operating procedures for each draft chemical assessment. The guidance includes assessment scoping, problem formulation and development, protocol development, and literature search and review as part of its major areas.

Also laid out are the program's steps to refining and studying evaluations, organizing hazard review, and extracting and displaying study results specific to health effects from epidemiology and toxicity studies. How to analyze and synthesize human and experimental animal data is also addressed, along with mechanistic information, evidence integration, hazard considerations and study selection for coming up with toxicity values, as well as ultimate derivation for those values.

The draft handbook is now open for a 90-day comment period. In a draft peer review charge to the National Academy of Sciences (NAS), EPA asked for input on elements including handbook organization and study evaluation methods.

Jennifer Sass, senior scientist with the Natural Resources Defense Council's health and environmental program, said the charge questions appear to prioritize "the state of the science." She largely praised the approach, but said she would have liked to see a bigger emphasis — within both the questions and the handbook itself — on conflicts of interest, particularly with regard to industry funding.

"What we would've liked to see is disclosure of funding sources, recognizing funding is a risk of bias," she said, noting that the handbook does include conflicts of interest as a component that can be noted in studies, but that they are not part of IRIS's formal process.

The American Chemistry Council has been a leading critic of the handbook's delayed release. In 2018, ACC pushed NAS to release a draft handbook for comment and asked that it include sections on areas like conducting dose-response modeling and selecting final toxicity values. In a statement yesterday, the trade association said it welcomed the opportunity to provide comments on the draft.

"There are long-standing and well documented concerns from government and non-governmental organizations regarding the program's lack of transparency, productivity and inability to produce scientifically sound hazard assessments that meet EPA's needs on a consistent basis," ACC said. "The release of the handbook for comment is an encouraging sign that the agency may be addressing some of those concerns, including the long-standing over reliance by the IRIS program on outdated default assumptions."

One area of concern is the study on formaldehyde. IRIS has been studying formaldehyde since 1987 and was set to release an assessment of the chemical before EPA blocked it, according to a March 2019 GAO report.

Lawmakers and environmental groups have worried any review of formaldehyde could be compromised by David Dunlap, deputy assistant administrator for science policy in EPA's Office of Research and Development.

Dunlap previously worked as a chemicals expert for Koch Industries Inc., which produces formaldehyde. While he signed an ethics agreement recusing himself from "any matters related to the formaldehyde IRIS assessment for the duration of

my EPA tenure," emails obtained by *Politico* in 2019 indicated he has taken part in discussions around the issue (*E&E Daily*, Dec. 12, 2019).

IRIS has also been a target for GOP lawmakers during the Trump administration (*Greenwire*, Feb. 2, 2018). An April 2020 GAO report found IRIS needed "far more chemical assessments" than the program currently produces. That report said EPA leadership needed to provide an agencywide strategy for addressing gaps around data and guidance for toxicity information due to IRIS shortcomings.

Senate signals growing priority for PFAS

E.A. Crunden, E&E News

https://www.eenews.net/eenewspm/2020/11/10/stories/1063718221?utm_campaign=edition&utm_medium=email&utm_source=eenews%3Aeenewspm

Multiple Senate fiscal 2021 spending bills contain funding targeting "forever" chemicals in drinking water and firefighting foam, among other areas.

The 2021 spending bills, released today, offer an indicator of how high profile contamination from per- and polyfluoroalkyl substances (PFAS) has become, with related water, defense and agriculture costs mounting.

PFAS in drinking water remain a focus, given the risks the bioaccumulative chemicals pose for human health, including cancer.

The Senate Interior-Environment bill includes $1.2 million for work on testing and sampling of bodies of water, with priority given to drinking water sources.

No less than $6.3 million is included in the bill for drinking water-related human health priorities under EPA's PFAS Action Plan, with another $2.5 million allotted for water quality protection under that plan.

The bill's explanatory statement also references ongoing EPA conversations around setting a maximum contaminant level for PFAS under the Safe Drinking Water Act.

Funding for the Agency for Toxic Substances and Disease Registry in the same bill utilizes a $2 million increase provided in 2020 as "base funds" for the agency's PFAS work in 2021.

That bill also includes $1 million for EPA actions relating to commerce under the Toxic Substances Control Act and the Toxics Release Inventory.

The Energy-Water bill, meanwhile, would direct EPA and the National Institute of Environmental Health Sciences' Superfund Research Program to use supercomputers to study the toxicology of PFAS.

Another focus is the disposal of PFAS-laden firefighting foam (AFFF), used in military training and operations.

The Department of Defense is required to phase out fluorinated firefighting foam by October 2024. The proposed Pentagon spending bill recommends almost $353 million "to address costs associated with remediating contamination caused by perfluorinated chemicals."

The Senate Appropriations Committee also noted concerns around the health implications PFAS poses for firefighters and first responders.

According to the bill's explanatory statement, lawmakers would request a briefing from the DOD Congressional PFAS Task Force regarding research on AFFF replacements. The Military Construction-Veterans Affairs explanatory statement also cites PFAS as an area of concern.

Referencing Department of Agriculture findings around PFAS in dairy milk and human exposure, the Agriculture bill's explanatory statement recommends $500,000 for indemnity payments to affected dairy farmers to purchase and remove contaminated livestock from the market.

The Food and Drug Administration would be tasked with reviewing "new scientific information" regarding PFAS in food packaging.

House spending measures, and proposed fiscal 2021 National Defense Authorization Act bills in both the House and Senate, also include policies and funding related to PFAS.

Lawyer Sees Subpopulation Risks As Initial TSCA Priority For Biden EPA

Rick Weber, Inside TSCA

https://insideepa.com/tsca-news/lawyer-sees-subpopulation-risks-initial-tsca-priority-biden-epa

A leading industry lawyer expects the incoming Biden administration to give higher priority to considering risks for vulnerable subpopulations such as low-income and minority communities when conducting chemical reviews under TSCA, saying the move is likely to be among the initial environmental reversals of Trump EPA policies.

"Two areas in at least the Toxic Substances Control Act [TSCA] space where I think you'll see changes is in the emphasis in performing risk evaluations on chemicals on the effects of those substances and the exposures of those substances in communities which historically may have been underrepresented in EPA risk evaluations," Lawrence Culleen, a partner at law firm Arnold and Porter, said during a Nov. 10 webinar on President-elect Joe Biden's energy and environmental agenda.

The webinar examined options for a Biden administration given the likelihood of a divided Congress with the Senate remaining in Republican control.

This means the new administration will be looking to existing statutory authority, the use of executive orders, increased enforcement and the role of guidance documents as it attempts to reverse what President Trump's critics have described as a deregulatory agenda that undermined environmental and public health protections.

Culleen's comments addressed potential changes for the TSCA program following the 2016 amendments which were signed by former President Barack Obama and implemented by President Donald Trump.

Noting Biden's commitments to bolster consideration of environmental justice, Culleen said he expects the incoming administration to emphasize the issue in its policy considerations, including in TSCA where the statute requires the agency to account for "potentially exposed and susceptible subpopulations (PESS)."

"So I think right out of the box, that's probably where we'll see changes," Culleen said. "I think they'll bring that to bear in the context where the statute requires that EPA take into consideration sensitive subpopulations when assessing risk and in choosing ways to evaluate chemicals," Culleen said.

Culleen's comments underscore calls from environmentalists and environmental justice advocates who have, so far, unsuccessfully urged the Trump EPA to formally account for risks to PESS in its next 20 TSCA chemical risk evaluations.

For example, Earthjustice and community groups from the Gulf Coast region in Texas and Louisiana argued in joint comments on EPA's draft scoping documents for the next 20 risk evaluations that the agency had a statutory obligation to account for the particular risks that communities adjacent to petrochemical facilities in the region face, rejecting EPA's arguments that other regulatory programs may already address those risks.

"EPA must identify people living in geographic areas near high-volume chemical facilities in Texas and Louisiana as potentially exposed or susceptible subpopulations," they wrote.

They argued that residents of those communities are "more exposed than the general population to the TSCA high-priority chemicals due to their proximity to industrial facilities that release these substances in high volumes." And they charged that residents of the area "are more susceptible than the general population to harm from exposure to the TSCA high-priority chemicals."

While environmentalists argue such considerations are mandatory, EPA has so far rejected their requests -- an approach that has drawn criticism even from some former agency officials. Jeff Morris, the former head of EPA's toxics office, wrote recently that the agency needs to bolster its explanations for how other programs address risks the chemicals pose to minorities and other susceptible groups.

But Morris argued that consideration of such risks is not mandatory. "EPA could strengthen its explanation of whether potential exposures or susceptibilities are based on geography," he said in a recently published article.

APA Requirements

While TSCA may provide an opportunity for the Biden administration to strengthen regulations, the Administrative Procedure Act (APA) might hinder Biden efforts to reverse Trump policies.

In particular, the Trump EPA's recently finalized rule, which goes into effect on Nov. 18, requires the agency to propose guidance documents for public comment before issuing them as final. Environmentalists and other Biden allies have criticized the rule as an attempt to hamper EPA efforts on industry compliance through bureaucratic red tape

Culleen says the rule could slow Biden administration efforts to quickly issue guidance to reverse Trump EPA policies or address other environmental compliance issues.

In addition, he says the APA's notice-and-comment requirements could make it difficult for the Biden administration to reverse the Trump guidance rule, which EPA Administrator Andrew Wheeler has touted as among his top agency reforms.

"I think it's an interesting question now because the agency just finalized a rule with respect to guidance and one might argue that to undo the rule on guidance one can't issue guidance," Culleen said He said the Biden administration will need to undo the rule which is itself an APA process.

"So it's a little quirky unless it comes undone through some other mechanism . . ., but I just want to throw out that I think that's a little curious," he said.

Culleen acknowledges the long-standing criticisms of EPA's reliance on guidance as the basis for the Trump rule which was issued as a result of an executive order, even while the timing could be politically questionable.

"For years EPA has been accused of unduly regulating informally through guidance, particularly in the chemical space, there's a lot of guidance documents with respect to pesticides, and with regard to test methods, approval processes, label reviews," Culleen said, "which are not codified per se but which are the life's blood of that program," he added.

Despite what some would say are justifiable reforms, if the Biden administration seeks to overturn or ignore the rule it might find itself facing a legal challenge, according to Culleen.

"And the rule with respect to guidance has made that a more, let's just say, constrained process, perhaps in a good way," he said.

"But I just would add that I think this administration, the incoming administration, if they want to issue guidance is, I think, perhaps poised to face a fight even on that issue as people who are affected by that may say 'Well wait a minute, you have to do that by your own rule, EPA, through notice and comment process.' So it's just one of the curiosities in my mind of how in an effort to de-bureaucratize and demystify EPA, the Trump Administration may have made it even more bureaucratic, and maybe deliberately so, given the timing of the final rule," Culleen said.

Science Rule

Another Trump rule that may pose a challenge for the Biden administration is EPA's proposed restrictions on the use of science in regulatory and policy decisions, Culleen notes. The rule, another Wheeler priority, requires data underlying EPA policies to be publicly available and independently verified.

While the measure has been subject to White House review since last month, the Trump EPA is expected to issue the final rule before the end of the year, raising questions about whether the incoming Biden administration might be able to withdraw it.

"I question how long, or not, that will stay in place," Culleen said. He noted that while the rule is generally supported by the chemical industry, it could undercut EPA approval of some substances.

"Ironically, registrants of pesticides oftentimes rely on data and studies which are performed in accordance with laboratory standards and submitted to the EPA as confidential submissions. The results of the studies are made public, but the body of the study sometimes they're not, and you could argue that EPA should not be able to rely on those studies in the context, or in light of the rule with regard to science transparency," he said.

"So, I don't know how long that rule will stand either," Culleen said.

The discussion by the panel of five Arnold and Porter lawyers was focused largely on climate change which is expected to be a major priority for the Biden administration, which in the face of a divided Congress, is not likely to get comprehensive climate legislation.

And yet a Trump administration rule on streamlining the National Environmental Policy Act process for reviewing the impact of industry and other projects could be a windfall of sorts for the new administration as it seeks to meet its goal of net-zero carbon emissions by 2050 through clean-energy investments.

"There are any number of initiatives, regulatory initiatives that the Trump administration pursued in the name of streamlining environmental review and permitting for major infrastructure projects" and some of those may be retained, said Ethan Shenkman, former EPA deputy general counsel in the Obama administration.

He noted that "it's not clear entirely whether the Biden administration will seek to reverse everything that happened in the Trump Administration with regard to environmental review and permitting because of course the Biden-Harris administration also very much supports a program of intensive infrastructure build out especially for renewable energy projects that are critical to the energy transition."

Shenkman said "all of those renewable energy projects whether their wind farms or solar farms, et cetra, are subject to the same vast complex of environmental review and permitting as other kinds of infrastructure projects."

"And so the new administration will, I think, also be considering how to streamline that process," Shenkman said

Democrats Crafting Plans To Enact PFAS Legislation Next Year, Dingell Says

Suzanne Yohannan, Inside EPA

https://insideepa.com/interview/democrats-crafting-plans-enact-pfas-legislation-next-year-dingell-says

Rep. Debbie Dingell (D-MI), the lead sponsor of legislation to require EPA to regulate per- and polyfluoroalkyl substances (PFAS), expects the House will prioritize passage of comprehensive PFAS legislation in the upcoming Congress, mirroring efforts from earlier this year, with high-ranking Democrats in both chambers already strategizing on plans.

In an exclusive Nov. 10 interview with *Inside EPA*, Dingell said she is "very optimistic" about the prospects for moving PFAS legislation through the new Congress and with President-elect Joe Biden taking office early next year. She said she believes the House will pass the same PFAS legislation it approved in early 2020, and will work with the Senate on it, with the Biden administration offering key support.

She declined to give specifics on which measures she would prioritize, saying she wants to wait to let the Biden administration get established.

But she expects it to mirror legislation she sponsored in the current Congress, H.R. 535, which passed the House with strong support from Democrats and backing from two dozen Republicans. That legislation was a sweeping bill that combined a dozen measures dealing with the class of thousands of PFAS chemicals, including provisions on drinking water, air quality, and waste cleanup.

Dingell said PFAS legislation will "be a priority" in the upcoming Congress for both the Energy & Commerce Committee -- the primary oversight panel on such a bill -- and on the House floor.

The incoming Biden administration also committed during its campaign to an environmental justice (EJ) plan that includes undertaking a number of regulatory measures on PFAS, potentially mooting the need for certain congressional measures House members have pushed unsuccessfully during the Trump administration.

Under a section of the plan devoted to improving drinking water quality, the Biden campaign commits to designating PFAS as "hazardous substances" under the Superfund law, setting enforceable standards under the Safe Drinking Water Act, prioritizing substitutes for PFAS through procurement, and accelerating toxicity studies and research on PFAS.

House supporters of the PFAS legislation, who are critical of EPA's lack of urgent response and regulation of the chemicals, over the past year have sought to include the Superfund provision and other PFAS measures in defense

legislation but have only seen success so far with more than two dozen measures that were mostly non-regulatory in nature.

For example, the Trump EPA has delayed by more than a year a proposal to designate two PFAS as Superfund hazardous substances and earlier this year issued a proposed decision to develop drinking water limits for those same two chemicals, after much prodding by lawmakers and others.

Planned Legislation

H.R. 535, the bill Dingell hopes to reintroduce in the upcoming Congress, included measures to require EPA to write federal drinking water standards for the two most studied PFAS -- perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) -- that protects the health of vulnerable subpopulations such as pregnant women and infants.

But it also included a five-year delay in enforcing PFAS drinking water standards to allow utilities to implement treatment techniques.

Further, it included measures to designate PFOA and PFOS as hazardous substances under the Superfund law within one year and set a deadline for EPA to determine within five years whether to list remaining PFAS under the law. Such designations would trigger cleanup liability for responsible parties that released the chemicals.

The bill also contained a requirement that EPA list PFOA and PFOS as hazardous air pollutants under the Clean Air Act, included measures that would block EPA from approving new PFAS for five years under the Toxic Substances Control Act (TSCA) and permanently bar EPA's use of the so-called low volume exemption when approving new PFAS uses.

The bill also would have required EPA to write effluent standards, pretreatment standards and water quality criteria for PFAS under the Clean Water Act.

House advocates for PFAS legislation could potentially have an easier time in the Senate, as Sen. Shelley Moore Capito (R-WV) is seen as likely to lead the Senate Environment & Public Works (EPW) Committee if Republicans retain control of the chamber. She would replace the current chairman, Sen. John Barrasso (R-WY), who opposed certain PFAS measures.

Capito worked closely with EPW Committee Ranking Member Sen. Tom Carper (D-DE) in 2019 on PFAS amendments to the fiscal year 2020 National Defense Authorization Act (NDAA), including provisions to regulate new uses of certain PFAS under TSCA and impose reporting requirements for 172 PFAS under the Toxics Release Inventory.

She and Carper also wrote an amendment that sought to list various PFAS as "hazardous substances" under the Superfund law, but Barrasso blocked the measure from consideration, fearing it would impose extensive cleanup liability.

Asked about the prospects of working with Capito, who is expected to be more supportive of PFAS legislation, Dingell remarked that she did not want "to get any Republicans in trouble," but said Carper and House Energy & Commerce Committee Chairman Frank Pallone Jr. (D-NJ) "are already talking strategy."

The potentially bright prospects for PFAS legislation next year come after the House blunted efforts to add regulatory-related measures on PFAS to the FY21 NDAA, which was slated for conferencing after the Nov. 3 elections. The House Rules Committee this past summer rejected a comprehensive amendment to the FY20 NDAA that mirrored H.R. 535, ruling it out of order because of budgetary points of order.

Former Top Officials Push Biden To Adopt Protective TSCA Approaches

Maria Hegstad, Inside TSCA

https://insideepa.com/tsca-news/former-top-officials-push-biden-adopt-protective-tsca-approaches

Former top Obama administration officials, academics and public health groups have crafted a comprehensive set of science and risk-based recommendations for the incoming Biden administration which they say would make EPA's TSCA program more health protective, including for chemical evaluations, environmental justice and other policy areas.

The new report, released Nov. 10, calls on the incoming administration to "put science and public health front and center at [EPA] to ensure that the most significant and pervasive threats to health from harmful chemical exposures are properly addressed."

Among other things, the report recommends that EPA adopt more conservative risk assessment approaches, such as unifying cancer and non-cancer assessments, place greater emphasis on consideration of environmental justice concerns, bolster its evaluation of advisors' potential conflicts of interest, strengthen its systematic review methods for evaluating research and increase investments in research and data infrastructure "to allow EPA to better identify and prioritize potential harms, evaluate risks, and analyze the effectiveness of interventions."

"There have long been serious problems with using the best science to inform chemical policy in the United States. Changes to the Toxic Substances Control Act (TSCA) in 2016 attempted to address these problems; however, the current administration's implementation of TSCA illustrates how the changes fall short," says the report, which was crafted by the Program on Reproductive Health and the Environment (PRHE) at the University of California, San Francisco, whose director is former EPA scientist Tracey Woodruff.

The report has been endorsed by experts and groups ranging from former Obama EPA research chief Tom Burke to Linda Birnbaum, the recently retired director of the National Institute for Environmental Health Science and the National Toxicology Program.

In addition, several former members of EPA's Children's Health Protection Advisory Committee, the North America chapter of the International Society for Environmental Epidemiology, the Autism Science Foundation and numerous academics and scientists with environmental groups have also backed the report.

Other groups, such as the Environmental Protection Network (EPN), a group of former EPA officials, have also offered a series of policy recommendations for how the next administration could strengthen the TSCA program.

By contrast, the report from PRHE offers a series of scientific and risk-based methods for making the TSCA program and other EPA programs more health protective.

Overall, the report urges the incoming Biden administration to "use the best available science to assess hazards and risks of chemicals to ensure better public health decisions, including a more representative definition of susceptible populations and using approaches to quantify risks for all health effects, both cancer and noncancer, at all anticipated levels of exposures."

Beyond that, the report divides its policy recommendations into six "critical areas" of chemical policy, systematic review, conflicts of interest, environmental justice, data infrastructure and research funding.

The chemicals policy section focuses largely but not exclusively on changes to EPA's implementation of Congress' 2016 rewrite of TSCA, while also focusing on some science policy fixes that could be implemented agency-wide.

Cancer & Non-Cancer Risks

For example, the authors urge EPA to unify cancer and non-cancer risk assessments by dropping the traditional assumption that chemicals that pose non-cancer risks have some threshold level below which exposure is "safe" and instead assume that any level of exposure can have associated risk.

EPA's Risk Assessment Forum has struggled to develop an approach to unifying risk assessments into agency-wide policy since the National Academy of Sciences addressed the issue in its 2009 "Science and Decisions" report to EPA. Traditional practice at EPA and elsewhere has been to express cancer risk as probabilities based on the assumption that there is some level of risk at any level of exposure, while noncancer risk estimates are expressed as 'safe' threshold level where there is no observed effect, known as a reference dose (RfD).

But the group argues that "[t]reating noncancer risk estimates similarly to how cancer risk estimates are treated would better reflect current scientific understanding of health risks, provide more useful and actionable information to the public and decision-makers about environmental health risks, and allow policymakers to better estimate the health benefits of environmental regulations."

The group recommends that EPA "[u]se established methods (e.g., probabilistic assessment) to quantify the level of risk for all identified health effects in parallel with RfD/point of departure calculation for every newly proposed noncancer benchmark (e.g., RfD) in an EPA IRIS assessment" and similarly to "quantify health risks from exposures and produce risk estimates under TSCA as part of risk evaluations. EPA should also use these risk calculations to quantify benefits under TSCA and better identify policy options to reduce exposures."

Other recommendations are specific to the TSCA program. For example, the authors call on EPA to revise its definition of potentially exposed and susceptible populations more broadly. Congress in its TSCA rewrite directs EPA to consider exposed and potentially susceptible subpopulations in its risk evaluations but does not define the term.

"Current scientific understanding indicates that intrinsic factors (such as pre-existing diseases) and extrinsic factors (such as stress due to food insecurity and/or poverty) can increase susceptibility to environmental chemical exposure risks. Under the current law, EPA must consider impacts of chemicals on potentially susceptible subpopulations; however its current definition does not capture the reality of susceptibility," the report argues.

"Naming the factors that should be considered for susceptible populations is an important step to ensure consideration of these factors in hazard and risk assessment," the report adds, before suggesting EPA look to the definition the Obama EPA proposed in the draft risk evaluation rule, one of the framework rules implementing TSCA reform that the Obama EPA proposed, but which were finalized by the Trump administration.

The report quotes an "expanded version of EPA's 2017 proposed definition" as "a group of individuals within the general population who, due to greater susceptibility may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, including but not limited to infants, children, pregnant women, workers, or the elderly. Susceptibility can be due to both intrinsic (e.g., life stage, reproductive status, age, gender, genetic traits) and acquired (e.g., pre-existing disease, geography, socioeconomic, racism/discrimination, cultural, workplace) factors when identifying this population."

The first 10 draft evaluations that the Trump EPA has produced under the TSCA reforms address a narrower set of susceptible groups, largely focused on life-stage and occupational exposures.

Environmental Justice

On environmental justice, a topic of interest for President-elect Joe Biden and Vice President-elect Kamala Harris, the report says that EPA should "incorporate environmental justice principles into every aspect of environmental policy and EPA's work" by taking steps such as using "cumulative environmental risk frameworks, full assessment of aggregate exposures, inclusion of legacy compounds and full health assessment of communities near manufacturing and disposal sites"; fully implementing President Bill Clinton's Executive Order 12898 on environmental justice and "reviving, expanding ... and revitalizing the federal Interagency Working Group on Environmental Justice."

The goal of such steps, the report says, is to "ensure that the routine outcome of our environmental laws and policies at all levels of government is equal protection, not environmental disparities."

On conflict of interest, the report recommends that "financial conflicts of interest from industry funding in environmental health research as well as industry ties on EPA advisory committees should be eliminated to the extent possible." To do so, it recommends that EPA "assess study-funding source and author financial conflicts of interests when evaluating study quality for hazard and risk assessment, and consider it a risk of bias" and balance members' conflicts of interest on advisory boards with members without such conflicts.

The report also urges EPA to strengthen its methods for conducting systematic reviews.

And it also recommends that EPA strengthen its data infrastructure by investing in systems to "support collecting, organizing and making accessible environmental and health data that allow the agency and the public to understand, monitor and act on environmental factors that influence health, resulting in more equitable public health safeguards."

Specifically, the report proposes that EPA "restore credibility and increase access to the results of its funded scientific research by implementing its 2016 Plan to Increase Access to Results of EPA-Funded Scientific Research" and also "apply the methods and tools of CalEnviroScreen nationally, creating a detailed visualization tool for the exposures and factors that increase a population's susceptibility to industrial chemicals."

Key Environmentalist Sees Long List Of Urgent TSCA Priorities For Biden

Maria Hegstad, Inside TSCA

https://insideepa.com/tsca-news/key-environmentalist-sees-long-list-urgent-tsca-priorities-biden

A leading environmentalist is identifying a long list of urgent priorities the incoming Biden administration will need to consider as it implements EPA's TSCA program, including redoing already-completed evaluations, broadening the scope of the next 20 evaluations and revising EPA's methods for assessing data quality.

In addition, said Bob Sussman, counsel to Safer Chemicals Health Families, the agency faces looming deadlines under the Toxic Substances Control Act (TSCA) to craft the first risk management rules, where officials are likely to face complicated policy questions, such as under what circumstances they are required to ban products that pose serious risks and how to ensure that regulatory mandates do not result in regrettable substitutions.

Sussman's comments, in an interview with *Inside TSCA* shortly after the Nov. 3 election, broadly echo proposals from others, including the Environmental Protection Network (EPN), a group of former agency officials, who earlier this year urged the next administration to quickly tighten EPA's risk evaluation methods, re-do the first 10 evaluations and regulate some "immediate" risks even while new evaluations are being finalized.

"I think that one of the first things the Biden administration will need to do is come to grips with the 10 initial risk evaluations and decide whether to unwind them to correct some of the mistakes of the Trump people," he said. "That's a big decision for them because it would mean going back to the drawing board and redoing some of the risk evaluations but I think it's important for them to take a hard look at that."

And while Sussman acknowledged that the latest of the those first 10 evaluations EPA has released -- such as those for carbon tetrachloride and a group of flame retardant chemicals -- have strengthened the risk conclusions from their earlier drafts, he argued the evaluations still deserve scrutiny, noting that two of the first four evaluations finalized face legal challenges.

"Even though a few of the risk evaluations seem to be moving in a slightly better direction than the drafts, there are still significant problems that need to be straightened out," he said.

EPA was due to complete its first 10 evaluations last June but has missed the statutory deadline for most of them.

With four of the 10 finalized, the agency is vowing to complete the remaining six by the end of the year. In the meantime, the statute's lengthy list of deadlines also trigged EPA's selection of and scoping for the next 20 chemicals it will evaluate.

EPA finalized those scoping documents in September and is beginning the 20 evaluations.

Not surprisingly, Sussman, a former top EPA official in the Clinton and Obama administrations, also considers this second group of evaluations to be a priority for review by Biden officials. "There's a need for immediate course correction on the ongoing 20 evaluations. It's going to be an immediate priority to look at how EPA is doing those 20 evaluations and determine whether to get some new direction to the EPA staff," Sussman said.

"That will involve a range of issues, including consideration of environmental releases, how to deal with aggregate exposures, how to deal with risk from consumer products, what assumptions to make on [workers' use of] personal protective equipment [PPE] and evaluating workplace risk and potentially exposed and susceptible populations."

Each of the issues he identified have already featured in environmentalists' critiques and pending legal challenges to EPA approaches in the first 10 draft evaluations, as well as in the framework implementing rules the Trump EPA finalized in 2017 and 2018.

Systematic Review

Sussman added that another area of immediate importance for the Biden team should be the systematic review process that EPA's toxics office developed for assessing the quality of studies and interpreting the evidence that forms the basis of its risk evaluations.

EPA has been repeatedly criticized by its Science Advisory Committee on Chemicals (SACC), environmentalists and academic systematic review experts for its methods, and for using an approach that had not undergone peer review on its 10 evaluations.

While the approach is now under peer review by a National Academy of Sciences committee, the next 20 evaluations are ongoing.

As a result, Biden's EPA team will "need to make some immediate decisions on the systematic review process. It's just not practical to wait several weeks and months to decide whether [to make changes to] systematic review because if they wait that's going to have, inevitably, a complicating impact on risk evaluations for the pipeline," Sussman said. "If they are going to do something different on systematic review, that decision time is now."

Beyond the existing chemical evaluations, Sussman noted that EPA is also facing impending statutory deadlines to draft and finalize risk management rules to mitigate the unreasonable risks EPA found in its final risk evaluations.

"EPA has a host of decisions to make on risk management for the initial 10 chemicals because the clock is running on those as well. From what I can tell, there is certainly a recognizing of the amount of work they have to do; outreach is all very good but I see a lot of policy and scientific issues that they're not taking a position on and they need to be doing that."

As an example of unaddressed policy issues, Sussman said that one "major question is under what circumstances you ban consumer products or industrial products. We would say that any consumer product that presents a serious risk, particularly an acute hazard, is a candidate to be banned unless there is some way of reformulating the product so it doesn't present those hazards. We don't have very much confidence in EPA issuing warnings or requiring labels that tell consumers how they should use these products. The track record of labels is not very impressive. That's an issue that EPA needs to come to grips with."

As another important example, Sussman questions how "EPA is going to address substitution, how strategic it's going to be about that. [Are they] going to see these rulemakings as an opportunity for green chemistry and try to move beyond some of the chemistries that are longstanding but problematic?"

Sussman was referencing a longstanding concern that regulation on chemicals can drive regrettable substitution, where an action on one chemical can lead to increased use of another chemical of concern, or an unknown chemical that later is found to be problematic.

Among the first 10 chemicals, regrettable substitution is "particularly an issue for the halogenated solvents" which represent almost half of the first 10 chemicals, with several more among the next 20, Sussman said. "There's the whole issue of regrettable substitution and whether EPA wants that to be the consequence of the rules and if not, what other path it's going to follow."

To address the problem, he suggests that EPA might beef up its voluntary green chemistry program known as Safer Choice, "or use some of the principles in Safer Choice to build a framework for substitution for acceptable chemicals. Maybe there need to be criteria [developed] for acceptable and unacceptable substitutes."

Chemical Tests

Beyond those immediate priorities on existing chemicals, Sussman has a lengthy list for the incoming administration, on topics ranging from pre-market review of new chemicals in the pre-manufacture notice (PMN) program to chemical testing orders.

"We would also like to see EPA put in place a meaningful section 4 testing program. Their track record on using section 4 is pretty dismal and it's time to really face up to the existence of data gaps for a lot of the chemicals that are in the queue for risk evaluation and to consider using their section 4 authority to require testing," Sussman said, voicing longstanding concern from environmentalists and other stakeholders that the Trump EPA has rarely used its expanded authority in reformed TSCA to order companies to test chemicals and provide that information to the agency.

Compared to new chemicals or pesticides, there is limited available information about many existing chemicals because there was no pre-market review required before these chemicals entered widespread use.

"I would really hope that there would be a revitalization of section 4 testing. Part of that is to require animal studies," Sussman said, acknowledging concerns from the animal welfare community about increased use of animal testing as well as language in the reformed TSCA directing the agency to reduce vertebrate animal testing wherever possible.

"There is the whole issue of animal testing and whether EPA should be requiring animal testing in the absence of validated, reliable [new alternate testing methods (NAMs)]. My own view is that it's essential they do that because otherwise we would be left with no scientifically sound way of generating data on toxicity. NAMs are just not ready to be put to use for regulatory purposes."

He adds that there are also "multiple aspects of the PMN program that need to be revisited and adjusted, to make that program more effective and reviewing new chemicals and detecting against potential risks."

Senators Seek To Bolster FY21 Funds For PFAS Research, Regulation

Diana DiGangi, Inside TSCA

https://insideepa.com/tsca-news/senators-seek-bolster-fy21-funds-pfas-research-regulation

Senate appropriators are proposing to provide tens of millions of dollars to EPA and other agencies in fiscal year 2021 to research and regulate per- and polyfluoroalkyl substances (PFAS), continuing their efforts to bolster funds to address the ubiquitous chemicals, though the incoming Biden administration is expected to step up such efforts.

In draft legislation released Nov. 10, the Senate Appropriations Committee is proposing to provide at least $64.5 million to EPA in FY21 -- an increase of more than $25 million over FY20 levels -- to help remediate contamination, assess the chemicals' risks, develop analytical assessment methods, and implement recently adopted regulations governing certain new uses of the chemicals under the Toxic Substances Control Act (TSCA) and requiring release reporting under the Toxics Release Inventory (TRI).

In addition, the draft legislation provides $2.5 million to the Agency for Toxic Substances and Disease Registry and $2.5 million to the National Institute of Environmental Health Sciences for their PFAS health research programs.

And the panel is also proposing to provide an additional $1.2 million to the U.S. Geological Survey to continue examining the reach of PFAS contamination in various waterbodies.

Such funding has grown for the agencies over the past few years as lawmakers and their constituents have become increasingly concerned about the risks posed by PFAS contamination -- concerns that have been exacerbated by Congress' and the Trump administration's failures to develop a suite of regulatory policies to address the chemicals.

But with the funds increasing, the appropriators are also asking EPA how it plans to spend the money. "Within 60 days of enactment of this act, the Agency is directed to brief with the Committee on planned [FY21] PFAS-related actions and provide the Committee with a spend plan which details funding at the program project level," according to language in the panel's explanatory statement.

Such a request from the committee may be helpful for the incoming Biden administration, which is expected to step up agency efforts to assess and regulate the chemicals.

The draft legislation is one of a series of bills the Senate appropriators released Nov. 10, which they say they hope to enact in an omnibus package in the coming weeks.

Congress and the White House face a Dec. 11 deadline to either enact bills funding agencies for the remainder of FY21, or another stopgap funding measure, to avoid a government shutdown.

Lawmakers are publicly signaling they want to avoid a funding lapse, despite only having four weeks to negotiate the differences between the bills.

But whether they are able to reach agreement remains to be seen as they must still move the legislation through the Senate and work out differences with their House colleagues.

For example, House lawmakers included report language requiring EPA to set aside as much as $2.5 million to assess whether exposure to PFAS and other pollution exacerbates the effects of the coronavirus, an issue that some Senate Democrats had sought to include in the Senate bill but which the committee's leaders rejected.

Nevertheless, the funding contained in the Senate Interior Appropriations bill is significant. For EPA, for example, the committee provides no less than $64.5 million "to continue to take action on PFAS, including addressing contamination, conducting research, and undertaking needed regulatory actions."

Of that, the committee says $20 million is for states to address PFAS "through remediation and cleanup," a continuation of funds provided in FY20.

The explanatory language says this is a $25.4 million increase above what was provided to EPA in FY20.

Explanatory Statement

The committee's explanatory statement also appears to earmark significant funds for several items that EPA has prioritized in its PFAS Action Plan.

For example, the language directs EPA to dedicate $1.5 million to implementing its TRI rule that requires industry to report on releases of dozens of PFAS, as well its Significant New Use Rule (SNUR) regulating certain long-chain PFAS.

The first round of industry TRI reports are due next July.

The Senate also requires EPA to dedicate about $27 million toward research provisions in its PFAS action plan aimed at "increasing research to reduce risks."

According to the action plan, these items include ongoing efforts by the agency's Integrated Risk Information System (IRIS) program to research the toxicity and effects of PFAS on human health, which includes completing pending assessments of GenX chemicals and perfluorobutane sulfonic acid (PFBS), and proposing draft toxicity values for perfluorodecanoic acid (PFDA), perfluorononanoic acid (PFNA), perfluorohexanoic acid (PFHxA), perfluorohexanesulfonate (PFHxS), and perfluorobutanoic acid (PFBA).

"The IRIS assessments will identify the potential human health effects from exposure to each assessed PFAS and will develop toxicity values, as supported by the available evidence. The assessments will evaluate both cancer and noncancer effects, including potential effects on the endocrine, hepatic, urinary, immune, developmental, and reproductive systems. EPA expects to propose draft toxicity values of these chemicals for public and scientific review in 2020," the action plan says.

EPA Releases Long-Sought Draft IRIS Handbook For NAS Peer Review

Maria Hegstad, Inside TSCA

https://insideepa.com/tsca-news/epa-releases-long-sought-draft-iris-handbook-nas-peer-review

EPA has quietly released a long-sought handbook detailing standard operating procedures for research office staff developing Integrated Risk Information System (IRIS) chemical hazard assessments, a program the Trump EPA has sought to sideline while boosting the nascent TSCA chemical evaluation program within EPA's toxics office.

Among other things, the draft handbook details the IRIS program's approach to conducting systematic reviews, a method for assessing the quality of studies used in risk assessments, as well as a first-time system for classifying chemicals' non-cancer risks.

Both issues reportedly delayed release of the draft document because of concerns from agency officials overseeing the Toxic Substances Control Act (TSCA) program.

EPA Nov. 9 posted on its website a draft version of its Office of Research and Development (ORD) "Staff Handbook for Developing IRIS Assessments" dated November 2020, along with a pre-publication version of a *Federal Register* notice announcing the document's release for public comment and peer review.

According to the notice, EPA will open a 90-day public comment period on the document, placing the end of the comment period after Inauguration Day and into the early days of the incoming Biden administration. EPA also indicates that it is releasing the document and charge questions for public comment in advance of a National Academy of Sciences (NAS) peer review.

The agency did not post the charge questions on its website with the other documents, and an electronic docket listed in the notice does not exist on the federal electronic docketing website.

IRIS officials began crafting the handbook following NAS' critical 2011 review of IRIS' draft evaluation of formaldehyde. The NAS report included an additional chapter -- outside the NAS committee's charge -- containing a series of recommendations for improving the IRIS assessment process as a whole.

Its publication led to an extended overhaul of the IRIS program, including implementation of systematic review as recommended by NAS, and a new process for developing and finalizing IRIS assessments.

But Congress' 2016 reform of TSCA and its new requirements that EPA's toxics office conduct risk evaluations of existing chemicals, once largely the province of IRIS, slowed agency efforts to reform the program.

IRIS' efforts were further stifled by the Trump EPA, which sought to sideline a program long disliked by industry, other regulated entities and some conservative state agencies for its conservative risk estimates that could drive costly management actions -- though Congress has repeatedly pushed back on administration efforts to stymie the program in appropriations bills.

In a Nov. 10 statement, the American Chemistry Council (ACC) welcomed the draft document's release, saying it will provide an opportunity to address "long-standing and well documented concerns from government and non-governmental organizations regarding the program's lack of transparency, productivity and inability to produce scientifically sound hazard assessments that meet EPA's needs on a consistent basis."

"The release of the handbook for comment is an encouraging sign that the agency may be addressing some of those concerns, including the long-standing over reliance by the IRIS program on outdated default assumptions," ACC said, adding that "EPA chemical assessment programs, including IRIS, must meet objective and transparent standards."

Systematic Review

The draft document's release comes after lengthy delays that sources said last year were driven in part by concerns from top officials in the Office of Chemical Safety and Pollution Prevention (OCSPP) who feared that ORD's systematic review approach in the handbook differs from methods they are developing to implement the revised TSCA.

"It never got released because there was a lot of discussion between OCSPP and ORD, and it wasn't apparent how that would get resolved," a source said last year. "People heard [the handbook] was dead, but ORD is using it -- but they don't make it public."

The newly released draft also emphasizes in its preface that the "handbook does not supersede existing EPA risk assessment guidelines and does not serve as guidance for other EPA programs. . . . The overall process of assessment development has not changed but is now supplemented by improved systematic review approaches that will help IRIS scientists to retrieve, organize, evaluate, synthesize, integrate, and present scientific information in a more structured and transparent manner."

One of the largest differences between the TSCA program's approach to systematic review and that of IRIS was a controversial approach the toxics office took to numerically rate the quality of individual studies, an approach the IRIS systematic review approach does not use.

An NAS committee is now peer reviewing the TSCA program's systematic review approach -- and at the committee's last meeting in August, an EPA official acknowledged that EPA is considering doing away with the numerical scoring system.

"The systematic review approaches described in this handbook are used to develop the human health assessment (hazard and dose-response assessment), which is the core component of risk assessment addressed by IRIS assessments," the new draft handbook states.

"These approaches include a literature identification strategy and evidence identification; evaluation of study methods; synthesis of the evidence from human, animal and mechanistic streams; integration of the evidence; and hazard identification. The IRIS assessment process also includes a systematic approach to the selection of studies for dose response to provide a transparent rationale for the decisions that guide the dose response assessment. However, most of the procedures described for conducting dose-response analyses are not amenable to the application of systematic review principles."

The handbook also seeks to address one criticism of systematic review -- that it can be time-consuming, a particular problem for a program long criticized even by its supporters as ponderous. "An overarching goal of these procedures is to promote an efficient and productive IRIS Program. In alignment with the Framework's emphasis on tailoring risk assessments to inform the decision-making process in a meaningful way, the IRIS assessment development process is intended to be 'fit for purpose.' The specific needs of a particular assessment will determine which procedures are applicable based on the scoping and problem formulation activities . . ."

Non-Cancer Risks

Like an earlier April 2019 version of the handbook that *Inside EPA* obtained last year, the newly released draft also includes a new system for describing and categorizing levels of evidence supporting non-cancer risks.

This approach is taken from IRIS' -- and other authoritative bodies like the Interagency Agency for Research on Cancer and the National Toxicology Program's -- longstanding practice of using labels describing the evidence linking a chemical to cancer potential, by describing a chemical as a "human carcinogen" or "likely to be carcinogenic to humans" or other findings based on a classification system specific to the scientific studies available.

IRIS has now crafted a similar system to label non-cancer risks in response to calls from the NAS.

But the weight of evidence characterization, or a descriptor, for non-cancer health effects associated with exposure to the chemical under assessment was identified last year by sources as another are of tension between the programs.

The non-cancer descriptors were a feature of the IRIS handbook four years ago, when former IRIS chief Ken Olden said he did not expect the handbook to be published until after his July 2016 retirement. At the time, he said the handbook "describes how we do systematic review," and also includes new "descriptors of non-cancer hazards."

They were also included in the 2019 draft.

The latest draft explains that IRIS' "interpretations regarding the strength of the available human and animal evidence (including mechanistic evidence informing biological plausibility) are judged and then considered together with mechanistic information on the human relevance of the animal data, coherence of the findings across human and animal studies, and the available information on susceptible populations and lifestages. This culminates in a final judgment about the extent to which the available evidence supports that the chemical poses (or is unlikely to pose) each hazard in humans."

The draft adds that "[c]onclusions can be drawn for a broader outcome category (such as neurotoxicity or carcinogenicity), or finer levels of organization may apply. For example, a subgrouping for neurotoxicity could involve behavioral effects, or on a finer level, hyperactivity, depending on the scope of the assessment, size of the database, and specificity of the available evidence."

The IRIS handbook includes a chapter on "evidence integration." The chapter notes that IRIS will continue to use the cancer descriptor as outlined in the agency's 2005 guidelines on cancer risk assessment, and includes a figure with descriptors that could be used for non-cancer effects ranging from "Evidence demonstrates" to "Evidence indicates (likely)" to "Evidence inadequate" and "Strong evidence supports no effect."

Senate Panel Offers TSCA 'Bridge' For FY21 But Eyes Future Fee Payments

Jeremy Bernstein, Inside TSCA

https://insideepa.com/tsca-news/senate-panel-offers-tsca-bridge-fy21-eyes-future-fee-payments

Senate appropriators are proposing to offer a $5 million advance to EPA's TSCA program in fiscal year 2021 to help cover costs while the agency begins collecting industry fees, an approach the House does not include in its funding bill, though senators are signaling they expect the agency to significantly increase future fee collections.

While the senators' proposed "bridge" funding for FY21 may help the agency in the current fiscal year until it begins to collect fees from companies, Senate appropriators indicate -- in report language released alongside new appropriations legislation -- that lawmakers eventually expect the agency to collect as much as $27 million in industry fees under the Toxic Substances Control Act (TSCA) in the next year.

Such expectations likely maintain pressure on the agency to impose and collect fees -- even as officials work to craft a rule that is intended to ease industry's fee burdens.

The fees provisions are included in the new bill funding EPA and other environmental agencies in FY21 that the Senate appropriations committee released Nov. 10. Senators say they expect the legislation to be part of an omnibus appropriations package that funds the federal government through the end of the fiscal year.

In addition to the TSCA fees language, the legislation and report language also includes provisions boosting funds for EPA to research the effects of per- and polyfluoroalkyl substances (PFAS) and other chemicals, and provides support for several pending chemical risk assessments, including the pending TSCA evaluation of asbestos.

"As the Agency continues to find the high risks associated with exposure to asbestos, the Committee encourages the Agency to finalize the [TSCA] risk evaluation and report to Congress as expeditiously as possible. The Agency must work with Congress to effectively protect communities from further exposure," the report language says.

Given that the current continuing resolution funding the government expires Dec. 11, Congress and the White House must move quickly to either enact bills funding agencies for the remainder of FY21, or another stopgap funding measure, to avoid a government shutdown.

Lawmakers are publicly signaling they want to avoid a funding lapse, despite only having four weeks to negotiate he differences between the bills.

But it is not clear that lawmakers can resolve differences to quickly approve an omnibus package.

For example, Sen. Tom Udall (D-NM), the ranking Democrat on subcommittee that oversees EPA, said in a statement that while he welcomes appropriations committee efforts to craft an omnibus package, he plans to work to resolve a "number of outstanding concerns . . . starting with the funding level of the bill itself. We simply need more resources to fund programs that address existential threats such as climate change, imperiled species, and crumbling infrastructure."

Udall also raised concerns that the draft "continues a number of anti-environmental policy riders from previous years that would bind the incoming Biden-Harris administration before they are even in office and need to be removed."

Nevertheless, Udall -- one of the lead authors of the revised TSCA -- said that he expects he will be able to work out his concerns with the subcommittee chairman, Sen. Lisa Murkowski (R-AK). "Over the past six years, Chairman Murkowski and I have worked through countless tough issues and enacted several very good bills. I expect that this year will be no exception," he said.

TSCA Fees

EPA's October 2018 final fees rule set the framework for the agency to collect $1.35 million per chemical from companies for each of the next 20 risk evaluations of existing chemicals the agency is beginning to conduct under TSCA section 6.

The fee requirement extends to all domestic manufacturers and importers, including those who manufacture the chemicals as a byproduct or import articles containing the chemicals.

Companies faced a Nov. 3 deadline to notify EPA of any consortia they may have been formed to manage payments and allocate responsibilities. Payments are due Jan. 2, 2021, or 120 days after publication of the scope documents, but EPA has indicated it is considering options to delay our establish payment schedules because of the economic and health crisis.

The $1.35 million fee is to be split among the companies on the list for each chemical, based on a formula contained within EPA's fees rule. Small businesses, based on the number of employees, will receive an 80 percent discount.

Such collections are expected to fluctuate year to year, depending largely on the number of existing chemical evaluations EPA commences. The agency is required to have at least 20 evaluations in process at all times, with a three-year deadline for completing these evaluations.

EPA launched its first batch of 20 such evaluations earlier this year, triggering a large wave of invoices to chemical companies to collect the first-time fees associated with those chemicals.

Before the fee requirement took effect, Congress had provided EPA with bridge funding to help the agency scale up its new program to meet the numerous new responsibilities and deadlines the revised statute imposed.

But earlier this year, House lawmakers approved their version of the FY21 spending bill which ended the practice just as EPA was poised to announce the list of companies that are required to pay the fees.

However, the just-released Senate legislation restores the bridge funding, providing $5 million to "remain available until expended, for necessary expenses of activities" under TSCA section 26(b)(1).

Reiterating past years' bridge funding language, the legislation says that any of the funds it provides from the agency's general fund must be entirely offset by any TSCA fees it collects. And any additional funds over $5 million the agency collects from TSCA fees in FY21 "shall be deposited in the 'TSCA Service Fee Fund' as discretionary offsetting receipts in fiscal year 2021, shall be retained and used for necessary salaries and expenses in this account, and shall remain available until expended."

EPA's toxics chief Alex Dunn has told industry officials that the upcoming industry fees are "absolutely critical" to the TSCA program and the agency is expecting to include $20 million in fees in the program's budgets going forward.

But chemical and other industry groups are seeking to ease the fee requirements, both in the short- and long-terms, especially since the pandemic cut their cash flow.

EPA has agreed and recently floated to the White House Office of Management and Budget (OMB) a proposed rule, slated for release before the end of the Trump administration, that would codify a series of categorical exclusions and other flexibilities under the fee program.

EPA plans to revise the fees rule is proving controversial as environmentalists say the agency needs to raise fees to cover the costs of its evaluations.

EDF lead senior scientist Richard Denison, who was slated to meet with OMB officials Nov. 10 to discuss the proposal, has argued that EPA has underestimated the baseline costs for implementing TSCA sections 4, 5 and 6 which the fees are intended to support, and that the fees need to be increased.

He has also argued that EPA lacks authority to grant the kinds of waivers it suggested it will provide.

EPA's rulemaking is also stoking controversy with chemical manufacturers and downstream users, who are at odds over the agency's methods for calculating fee payments.

US ATSDR sets risk level of intermediate oral exposure to chlorobenzene

Chemical Watch

https://chemicalwatch.com/177603/us-atsdr-sets-risk-level-of-intermediate-oral-exposure-to-chlorobenzene

The US Agency for Toxic Substances and Disease Registry (ATSDR) has set a minimal risk level (MRL) for intermediate oral exposure of 0.07 milligrams per kilogram of bodyweight per day (mg/kg/day) in its final profile of the chlorinated solvent chlorobenzene.

However, it was unable to set MRLs for the other five exposure situations it considered owing to "insufficient data".

Chlorobenzene is used as a solvent in formulating pesticides, manufacturing diisocyanates and degreasing automobile parts. It is also used as a chemical intermediate in the production of other chemicals.

Workers exposed to chlorobenzene in the air have reported health effects such as headaches, dizziness and sleepiness, the profile says. Studies in animals indicate that high doses of the substance may damage the liver, kidneys and central nervous system.

For the general public, the most likely sources of exposure are from air, drinking water and contaminated food, the profile says.

However, chlorobenzene has been detected in "only very small quantities" in these sources, it adds. "The potential for toxic exposure to chlorobenzene via the water supply may be somewhat limited by the relatively low solubility of chlorobenzene in water," the profile says.

The profile does not set an MRL for:

- inhalation exposure of any kind, which comprise chronic, intermediate and acute situations;
- chronic oral exposure; or
- acute oral exposure.

As a class, chlorinated solvents are currently under a relatively high degree of regulatory scrutiny. They account for 11 of the 30 substances prioritised for risk assessment under US

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As a class, chlorinated solvents are currently under a relatively high degree of regulatory scrutiny. They account for 11 of the 30 substances prioritised for risk assessment under US TSCA. However, chlorobenzene is not one of those substances.

The ATSDR has also published final profiles for:

- 2-butanone;
- 1,2-diphenylhydrazine; and
- mirex and chlordecone.

EPA facing lawsuits over atrazine, dicamba

Steve Davies, AgriPulse

https://www.agri-pulse.com/articles/14813-epa-facing-lawsuits-over-atrazine-dicamba

The Environmental Protection Agency is facing more lawsuits over herbicides, including a challenge from grower groups over new dicamba restrictions and a lawsuit from environmental groups over atrazine.

The grower lawsuit (https://agri-pulse.com/ext/resources/pdfs/courts/dicamba-asacomplaint.pdf), brought by the American Soybean Association and Plains Cotton Growers in Texas, alleges that expanded buffer zones to protect endangered species and downwind crops from dicamba applications will severely cut into their crop acreage and that cutoff dates will heighten weed pressure. EPA recently approved (https://www.agri-pulse.com/articles/14742-epa-oks-dicamba-use-for-five-more-years) five-year registrations for Bayer's Xtendimax, BASF's Engenia and Syngenta's Tavium, but included a June 30 cutoff date for soybeans and July 30 for cotton. The agency also expanded downwind buffer zones to protect endangered species and other crops and vegetation from off-target movement. "Cotton and soybean growers planting in the nearly 300 counties nationwide potentially inhabited by listed species are subject to 310-foot downwind application buffers, and a 57-foot omnidirectional buffer, each ostensibly designed to achieve [Endangered Species Act] compliance," the ASA/Plains Cotton Growers lawsuit says. "Growers must also abide by a 240-foot, universally controlling, downwind FIFRA application buffer."

They are asking the court to rule that those restrictions are "arbitrary and capricious" and have EPA review them under the Federal Insecticide, Fungicide, and Rodenticide Act and the Endangered Species Act. But the groups also make clear they do not want the court to take dicamba products away from them. They are asking the U.S. District Court for the District of Columbia to remand the dicamba decisions to EPA without vacating the overall decisions.

They also ask the court specifically to uphold EPA's determinations that use of the herbicides won't affect certain species. ASA President Bill Gordon, a soybean grower from Worthington, Minn., said while "ASA appreciates EPA's work on re-registering dicamba for use on soybeans and believes dicamba can be a critical tool for combating herbicide-resistant weeds," there also are "two significant flaws" with the decision: the cutoff date and the buffer requirements.

"We are confident that remanding this back to EPA for further consideration can lead to a better solution for growers who could be negatively affected if planting is delayed, for example by adverse weather conditions or late weed emergence, past June 30 or whose production volume would be significantly lessened by the wider buffer zones," Gordon said.

"Without dicamba products in their arsenal, many farms would be largely defenseless in their fight against weeds," the groups' lawsuit says. "A handful of other herbicides remain available but are often only partially effective, if at all." The grower groups say the new restrictions would hamper production.

A soybean farmer with a 54-acre field, for example, who "happens to live in one of the several hundred ESA-restricted counties," could lose nearly a third of farmable land because of the species buffer, the complaint says. In addition, for cotton, the lawsuit says "the application restrictions' July 30 cutoff date exposes many growers to potentially devastating weed pressure during the heart of cotton's growth cycle, often deep into August and September." Environmental groups that successfully challenged prior dicamba registrations plan to sue again, but have yet to file a complaint. Center for Food Safety Legal Director George Kimbrell would say only that with its recent decision, "EPA continues down the wrong path of more damage from dicamba, and we're evaluating all options to protect farmers and wildlife habitat."

Atrazine is another widely used herbicide coming under scrutiny, as environmental groups prepare to move forward (https://biologicaldiversity.org/w/news/press-releases/lawsuit-challenges-epa-reapproval-endocrine-disrupting-pesticide-atrazine-2020-10-30/) with a lawsuit in the U.S. Court of Appeals for the Ninth Circuit. The Center for Biological Diversity (CBD), Rural Coalition, Pesticide Action Network North America, Center for Food Safety and Beyond Pesticides

have petitioned the court to review the agency's Sept. 2 interim registrations not just for atrazine, but for the related herbicides propazine and simazine.

The petition filed in the Ninth Circuit includes few details, saying the interim decisions "lack support in substantial evidence" and seeking to have them "set aside." CBD Senior Scientist Nathan Donley said the lawsuit would focus on compliance with FIFRA, which requires applicants for registration to show their products won't cause "unreasonable adverse effects on the environment," including risks to people. The groups will rely in part on the Ninth Circuit's decision earlier this year vacating dicamba registrations, in which the court said EPA "substantially understated the risks" of over-the-top applications of dicamba and did not acknowledge the economic and social costs of using dicamba.

In announcing its interim atrazine decision, EPA said it was imposing new personal protective equipment requirements, but Donley said because of the heat farmworkers have to work in, "a lot of the PPE requirements are probably not going to be followed." He also said EPA had removed additional safety factors that would have resulted in greater restrictions on the products. "It's something we're seeing them doing a lot," Donley said. "They're erasing protections at the risk assessment phase, and then when it comes to the decision phase, they're putting in place greater protections or restrictions and sort of glossing over what they did the previous step."

EPA lowered the amount of atrazine and simazine that can be applied to turf, for example, but Donley said those would have been greater if the safety factors were taken into account. On the other side of the issue, Gary Marshall, CEO of the Missouri Corn Growers Association and chair of the Triazine Network, pushed back against claims that EPA's decision threatens public health and the environment.

"Absolutely, EPA spent a lot of time with their legal team to make sure their policy decision would be entirely defensible in court," Marshall told *Agri-Pulse.* "Our number one goal, good or bad, was for the EPA to 'follow the science.' They did that with this ruling."

He said environmental groups that are suing are using old studies. "They completely ignore all the new science which EPA has thoroughly reviewed from the last 15 years," he said. "These products are the most heavily researched compounds in the history of crop production and are among the safest to use for the environment, human safety and for the safety of aquatic life." The environmental groups also allege EPA's changes to the registration will allow more atrazine in waterways. EPA has previously denied that.

The Challenges to Effective Weed Management

Eric Sfiligoj, CropLife

https://www.croplife.com/crop-inputs/herbicides/the-challenges-to-effective-weed-management/

Controlling herbicide-resistant weeds was already a major challenge for ag retailers and their grower-customers. And this situation has been made more difficult because of a number of factors that impacted agriculture during 2020 — many of which will continue to plague the market during the upcoming growing season.

At last count, the number of herbicide-resistant weeds globally had skyrocketed past the 500 mark. Of these, there are varieties that have evolved resistance to 23 of the 26 known herbicide sites of action and 167 different herbicides overall.

To gauge just how difficult controlling weeds has become, *CropLife*® magazine sent out a brief survey to its readers in October. The results were eye-opening, to say the least.

When asked about the current state of weed control in agriculture, the majority of respondents (40%) indicated this was "very volatile, as bad as I've ever seen it." Another 37% wrote that weed management was volatile, "but not as bad as it once was." Only 16% of respondents believed weed control today was "better" than it had been during prior growing seasons. The remaining 7% weren't entirely sure what the current state of herbicide-resistant weed control was in their areas of the country.

Of course, fighting the resistant plants within the crop fields has only been part of the battle for agriculture of late. For several years now, popular herbicides for controlling weeds such as glyphosate have been mired in lengthy court fights, potentially impacting their continued use as management tools. During 2020, this came to a head of sorts for one herbicide, as the Ninth Circuit of Appeals vacated the 2018 registration of dicamba for use. A subsequent ruling from the EPA allowed users to apply dicamba through the end of July, however.

More Days in Court

According to the survey, agriculture expects more such court battles to take place in the months and years ahead. Slightly more than half (51%) say that court battles over crop protection products will increase in frequency during 2021 and beyond, with another 36% believing the current high level of legal activity will remain constant for the foreseeable future. Only 2% think that courtroom attacks on crop protection products will decrease.

Furthermore, these constant courtroom battles may have already tampered the future growth ability for dicamba. According to the survey, one-quarter (25%) of respondents say sales of the herbicide in 2021 will be flat, with another 17% believing declining sales are in dicamba's future. The majority, 36%, think that growers will keep using dicamba in the 2021 growing season, "but begin looking for alternatives to it." Only 22% of respondents believe dicamba will keep growing sales/market share going forward.

Weed Control Changes Ahead

Naturally, weed control management will begin to alter somewhat because of all these challenges. For one thing, with all the legal issues impacting post-emerge products, observers see bigger market opportunities for pre-emerge products. In fact, according to the survey, 68% of respondents predict pre-emerge product use will become more widespread than it is today, with another 22% saying usage in this sector will increase "a little more" during upcoming growing seasons.

"Pre-emerge products will be extremely important for 2021," says Derrick LeBeau, an Agronomic Services Representative for Syngenta. "They will offer growers an effective way to get their fields clean and combat hard-to-control weeds on the front end."

Beyond this, survey respondents predict that weed control management will continue to develop strategies to fight herbicide-resistant weeds. One recent trend respondents think will dominate weed control management in the 2021 growing season is one that has already shown some recent popularity — "cocktail mixes" of different active ingredients that operate with different modes of action. According to the survey, 60% of respondents think these "blended products" will become the norm moving forward.

This month, another example of this kind of herbicide was introduced by Corteva Agriscience. Called Kyber, it's a pre-emerge product featuring a blend of three active ingredients — metribuzin, flumioxazin, and pyroxasulfone.

As for the rest of the ways weed control management might change in the years ahead, 14% of respondents believe ag retailers and their grower-customers will begin looking at using biological products to battle herbicide-resistant weeds. Another 22% think the effort to bring new active ingredients to the agricultural market will accelerate from its current pace (more than one decade from lab to field). The remaining 4% foresee "no changes" to weed control.

US EPA Assessment Shows Atrazine Causes Massive Harm to Endangered Species

Sustainable Pulse

https://sustainablepulse.com/2020/11/11/us-epa-assessment-shows-atrazine-causes-massive-harm-to-endangered-species/#.X61-s2hKiUn

The finding is a result of the agency's first-ever nationwide assessment of an herbicide's harm to protected species, an analysis that's required by the Endangered Species Act.

The assessment's release comes just two months after the EPA reapproved the pesticide's use for another 15 years.

"Finally the EPA has been forced to acknowledge atrazine's far-reaching harms," said Nathan Donley, a senior scientist at the Center for Biological Diversity. "This alarming assessment leaves no doubt that this hideously dangerous pesticide should be banned in the U.S., just as it is across much of the world."

Atrazine is a widespread pollutant of groundwater and drinking water, has been linked to increased risk of cancer and reproductive problems in people, and can chemically castrate male frogs at extremely low concentrations, including those allowed in drinking water.

Despite being banned in more than 35 countries, including the entire European Union, it remains the second-most used herbicide in the United States after glyphosate.

Today's draft assessment is part of a legal agreement between the Center and the EPA. It found that atrazine is likely to harm 1,013 protected species, or 56% of all endangered plants and animals in the nation. Species harmed include the highly endangered whooping crane, California red-legged frog and San Joaquin kit fox.

The risk of ongoing widespread harm was found despite major changes to the pesticide's use restrictions announced by the EPA in September that effectively ban atrazine in Hawaii, on forests, on Christmas tree farms and along roadsides. For endangered species found outside the proposed ban areas, the finding of harm was nearly 100%.

Today's draft assessment was conducted using a guidance document finalized earlier this year by the Trump administration, dubbed the "Revised Methods," that disregarded the recommendations of the National Academy of Sciences and ignored the mandate of the Endangered Species Act to give imperiled wildlife and plants the benefit of the doubt when evaluating the range of impacts caused by exposure to pesticides.

By using this new guidance — which precludes consideration of downstream runoff of pesticides into water bodies where endangered aquatic species, like fish and snails, live — the EPA has likely underestimated the true severity of the risk many species face from atrazine exposure.

Atrazine is widely present in U.S. surface waters and drinking-water supplies. Earlier this year the EPA granted a request from atrazine's maker, Syngenta, to suspend monitoring atrazine in waterways for 2020. The EPA had denied Syngenta's previous request to stop monitoring atrazine in waterways, because it "...has continued to show atrazine concentrations of potential ecological concern in the most vulnerable watersheds, even when stewardship programs are employed."

"With this troubling finding, even the EPA has been forced to acknowledge the unacceptable harm caused by atrazine," said Donley. "It's beyond me how it can still be approved for such widespread use across this country."

Draft evaluations for pesticides very similar to atrazine, simazine and propazine, were also released today.

In September the EPA announced it would be reapproving atrazine for the next 15 years, eliminating longstanding safeguards for children's health, and allowing 50% more atrazine to end up in U.S. waterways. The Center for Food Safety, Center for Biological Diversity and a coalition of public-interest groups sued to challenge that decision last week.

PPG works on approval for antimicrobial paint that can kill Covid-19

Julia Mericle, Pittsburgh Business Times

https://www.bizjournals.com/pittsburgh/news/2020/11/12/ppg-works-on-approval-for-antimicrobial-paint.html

Pittsburgh-based PPG Industries Inc. joined forces with Corning Inc. to create a paint product that incorporates Corning's new glass-ceramic technology that kills coronavirus, according to a news release.

Corning demonstrated that it new technology, called Guardiant, can kill more than 99.9% of the virus that causes Covid-19. The technology underwent EPA-approved tests that showed that coatings and paints containing Guardiant showed antimicrobial effectiveness after a simulated six years of scrubbing.

"Our scientists have developed this unique paint additive using our highly engineered glass-ceramic technology," Wendell Weeks, chairman and CEO of Corning Inc., said in a prepared statement. "We are excited about the new lab results and look forward to working with our valued partner PPG."

PPG and Corning seek EPA registration for a paint product with this technology.

"We know that now more than ever, our customers are seeking multiple layers of protection as they navigate the Covid-19 pandemic," Michael McGarry, PPG chairman and CEO, said in a prepared statement. "Following registration with the EPA, we look forward to launching a paint product in the coming months that contains Corning Guardiant, providing customers with an additional safeguard from the coronavirus in areas that pose a higher health risk."

Study Links Worse COVID Outcomes To PFAS But Urges More Research

Diana DiGangi, Inside TSCA

https://insideepa.com/tsca-news/study-links-worse-covid-outcomes-pfas-urges-more-research

A new study indicates that worse outcomes from COVID-19 can be linked to higher background exposure to certain per- and polyfluoroalkyl substances (PFAS), though the study's authors are calling for more research into cases where patients have higher PFAS exposures than those assessed in the study.

The study, which was issued online late last month but has not yet been peer reviewed, looked at plasma samples from 323 Danish subjects who had contracted the coronavirus and measured background exposures to "five PFASs known to be immunotoxic," including perfluorobutanoic acid (PFBA).

PFBA is a breakdown product of other PFAS used in stain-resistant fabrics, paper food packaging and carpets, according to EPA.

Researchers found that "Increased plasma-PFBA concentrations were associated with a greater severity of COVID-19 prognosis, and this tendency remained after adjustment for sex, age, comorbidities, national origin, sampling location and time," the study's abstract concludes.

But the study calls for more data. "Given the low background exposure levels in this study...the role of PFAS exposure in COVID-19 needs to be ascertained in populations with elevated exposures," the study says.

Despite its limited finding, the study nevertheless highlights congressional efforts to provide federal funds to assess the links between PFAS exposure and the effects of COVID-19.

Top Senate Democrats have called for appropriators to include funding in EPA's fiscal year 2021 spending bill to study the connections between PFAS exposure and the virus, and have also pressed top health officials to allocate funds to study the issue.

While lawmakers have yet to secure the funds they are seeking for such studies, federal agencies and private researchers are already pursuing several research projects to assess the ways that PFAS exposure could exacerbate the effects of the coronavirus, including whether PFAS exposure reduces people's resistance to COVID, whether PFAS contributes to overreaction to the virus by the immune system (thereby worsening symptoms); and whether PFAS exposure reduces the efficacy of a COVID vaccine.

Dr. Laurel Schaider, a research scientist at the Silent Spring Institute (SSI), said recently that the Centers for Disease Control and Prevention (CDC) is finding ways to "incorporate PFAS into some of their COVID studies," and that "researchers who are conducting studies in PFAS-affected communities are considering how best to incorporate COVID."

Efforts to study the issue come after the CDC and the Agency for Toxic Substances and Disease Registry (ATSDR) earlier this summer issued a statement acknowledging the possibility that exposure to PFAS could harm the immune system, undercutting the ability of COVID-19 patients to fight off the virus.

The lead scientist on the current study, Dr. Phillipe Grandjean, a Harvard University professor who has long studied the health effects of PFAS, has been previewing upcoming results from this study since the summer.

"It looks to me like PFAS would be a main culprit that we should look at because they are everywhere," Grandjean said. "I would certainly think that either [National Institutes of Health] or CDC should fund studies where they look at these affected communities that have been drinking PFAS-contaminated drinking water for some time, probably decades."

Grandjean's study was funded by Denmark's Novo Nordisk Foundation, as well as by Grandjean's funding from the National Institute for Environmental Health Sciences.

EPA Accepting Comment on IRIS Handbook, Draft Charge Questions for Reviewers

Lynn L. Bergeson and Carla N. Hutton, B&C TSCA Blog

http://www.tscablog.com/entry/epa-accepting-comment-on-iris-handbook-draft-charge-questions-for-reviewers

The U.S. Environmental Protection Agency (EPA) announced on November 10, 2020, that the Integrated Risk Information System (IRIS) Program released the *ORD Staff Handbook for Developing IRIS Assessments* (IRIS Handbook) for public comment. EPA states that the IRIS Handbook provides operating procedures for developing IRIS assessments, including problem formulation approaches and methods for conducting systematic review, dose response analysis, and developing toxicity values. The IRIS Handbook notes that it does not supersede existing EPA guidance and does not serve as guidance for other EPA programs. EPA will publish a *Federal Register* notice announcing the beginning of a 90-day public comment period on the IRIS Handbook and on the draft charge questions for reviewers in advance of a National Academies of Sciences, Engineering, and Medicine (NASEM) peer review. EPA will summarize comments received and provide them to the committee conducting the peer review. EPA has posted a pre-publication version of the *Federal Register* notice.

EPA Announces Proposed Updates to List of Pests of Significant Health Importance

Heather F. Collins and Barbara A. Christianson, B&C Pesticide Law and Policy Blog

http://pesticideblog.lawbc.com/entry/epa-announces-proposed-updates-to-list-of-pests-of-significant-health-impor

On November 4, 2020, the U.S. Environmental Protection Agency (EPA) published a notice in the Federal Register announcing the release of an updated list of pests of significant health importance for public review and comment. 85 Fed. Reg. 70146.

EPA, in coordination with the Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture (USDA), identifies pests of significant public health importance, and in coordination with the Public Health Service, develops and implements programs to improve and facilitate the safe and necessary use of chemical, biological, and other methods to combat and control such pests of public health importance. According to EPA, the list serves as a tool for private and public organizations, including local or state governments, departments of public health, pesticide registrants, and non-governmental organizations, when making decisions and plans about future public health actions.

Since this list's original publication in 2002, new vector-borne diseases have been identified and pests that had been previously thought of as benign or nuisance pests have been found to impact adversely public health. EPA, CDC, and USDA collaborated to update the list to incorporate significant changes regarding vector-borne diseases and related research, and eliminate gaps or ambiguities in the current pests list.

EPA states in the notice that the draft Pesticide Registration (PR) Notice 2020-X more precisely describes both the pests and expected public health impacts and adds several new pests (the brown dog tick) and public health impacts (Zika fever and coronaviruses like SARS-CoV-2) and that other pests have been renamed or grouped with similar species or removed altogether (hobo spider).

Draft PR Notice 2020-X describes the groups of pests and their potential impact on public health as follows:

- ***Arthropods***: The listed arthropods may cause asthma or trigger allergies, contaminate food, irritate skin, cause direct injury, or carry diseases such as epidemic typhus, trench fever, epidemic relapsing fever, malaria, encephalitis (St. Louis, Eastern, Western, West Nile, and LaCrosse), yellow fever, dengue fever, and many others.

- ***Vertebrates***: The listed organisms have the potential for direct human injury and can act as disease reservoirs for rabies and other diseases. The rats and mice include those that spread rodent-borne diseases and contaminate food for human consumption.
- ***Microorganisms and acellular particles***: This category includes listed bacteria, fungi, protozoans, viruses, virusoids, and prions. The microorganisms and acellular particles listed in this category cause diseases such as COVID-19, cholera, meningitis, Legionnaire's Disease, and many others.

The complete list of pests is identified in draft PR Notice 2020-X in Appendix A.

EPA states that the list does not affect the regulatory status of any registration or application for registration of any pesticide product.

Comments on the draft PR Notice are due on or before **January 4, 2021**, in Docket EPA-HQ-OPP-2020-0260.

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